

Figure 1

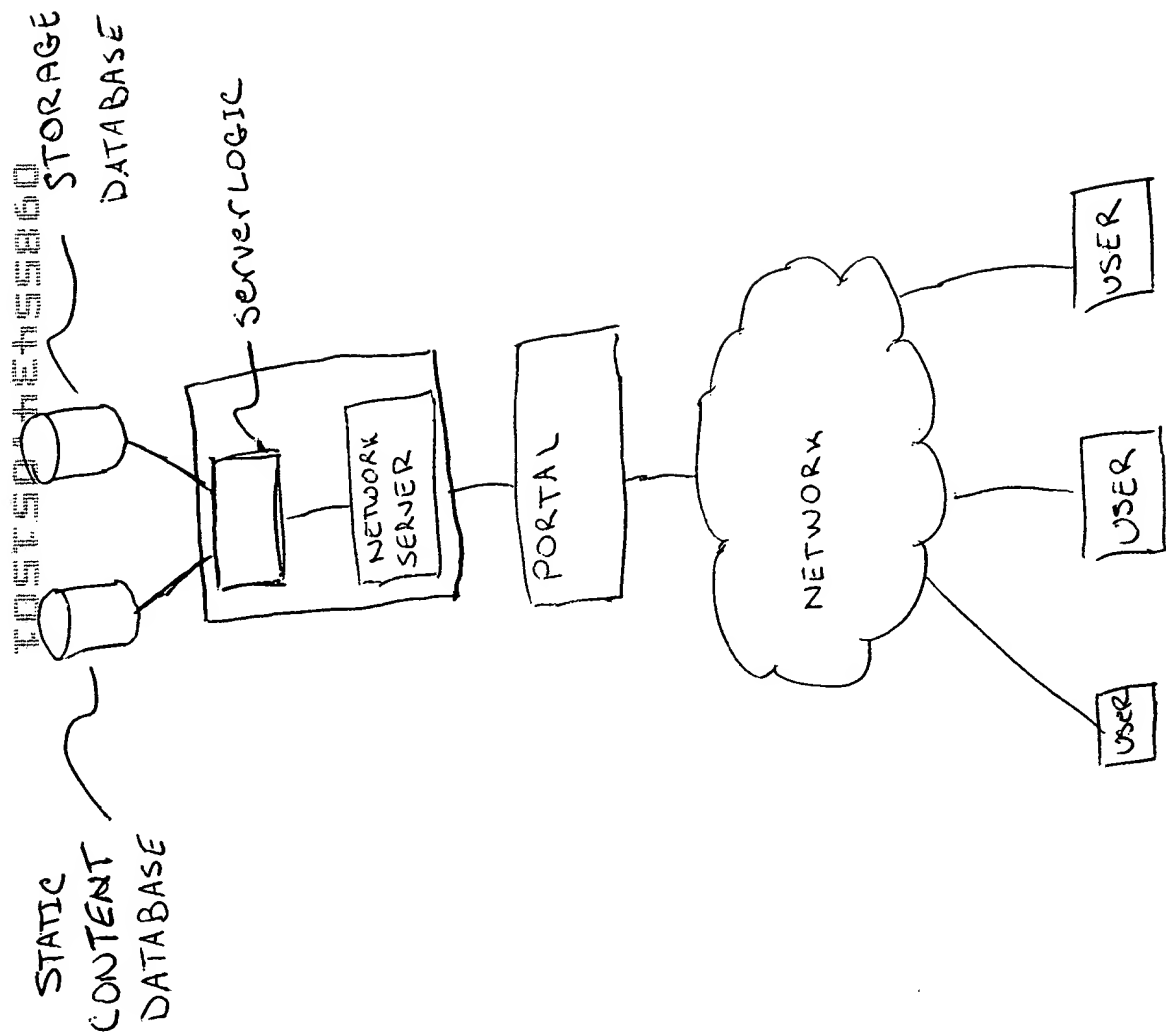
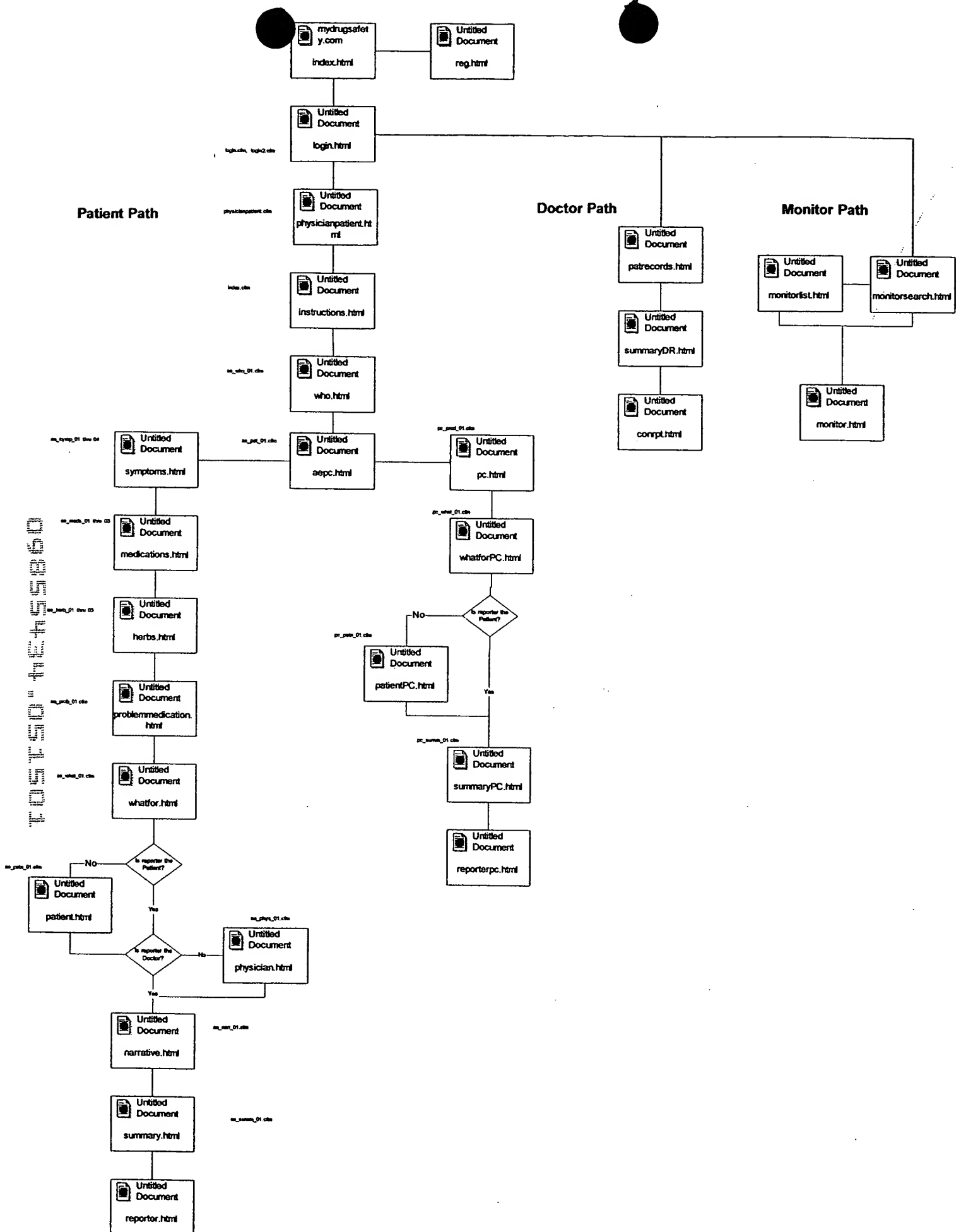


Figure 2



Portal Pilot Workflow

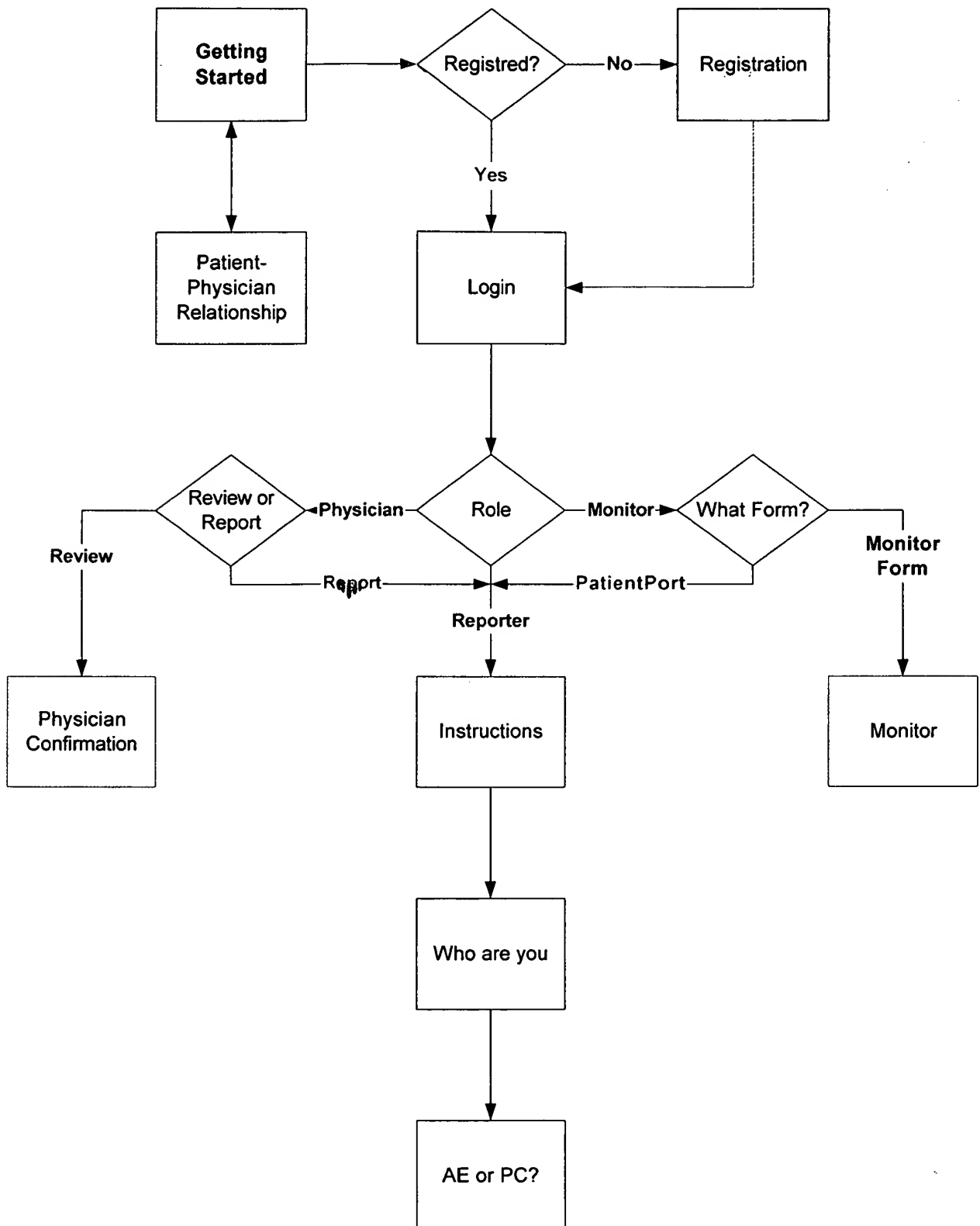


Fig 3a

AE or PC Guided Reporting

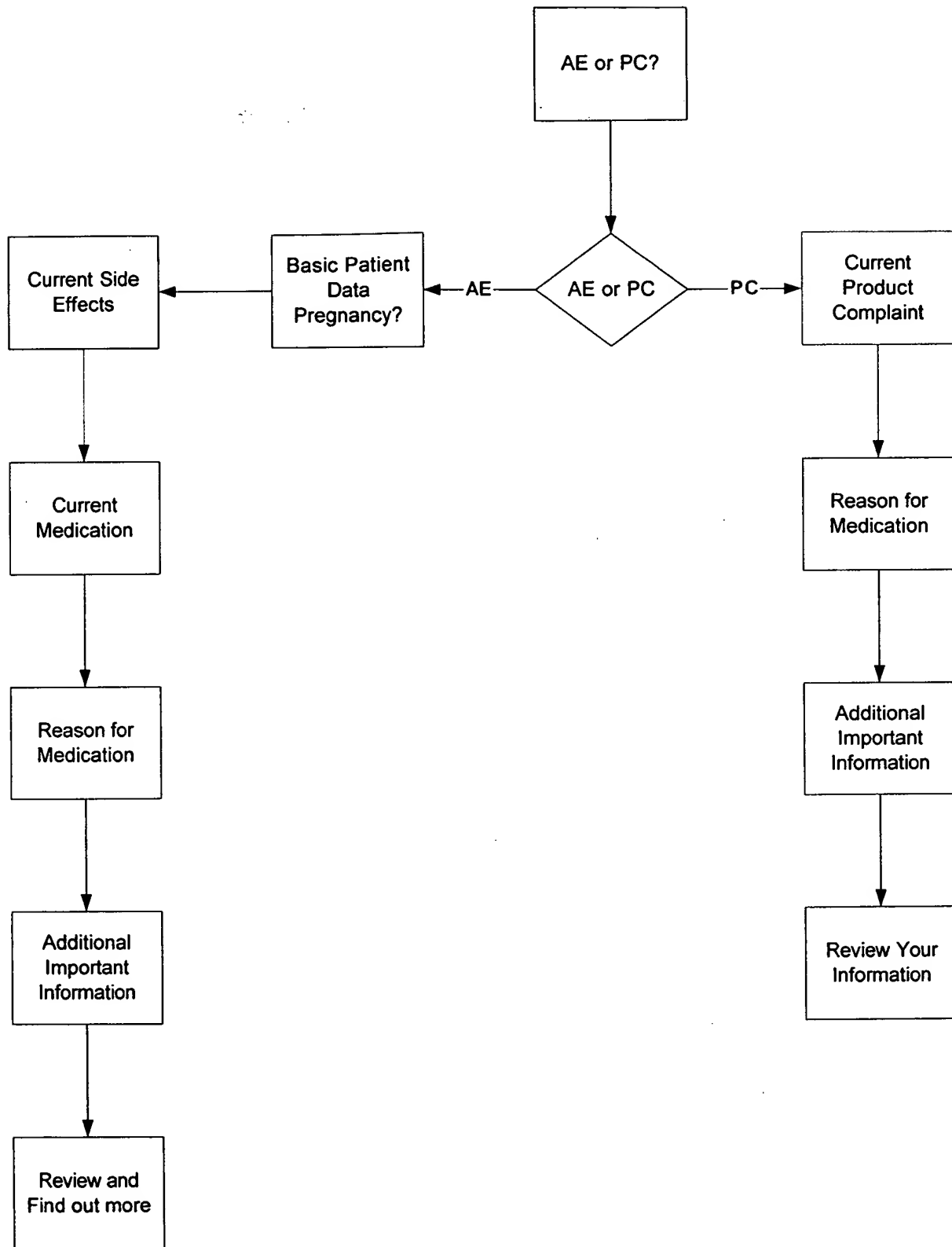
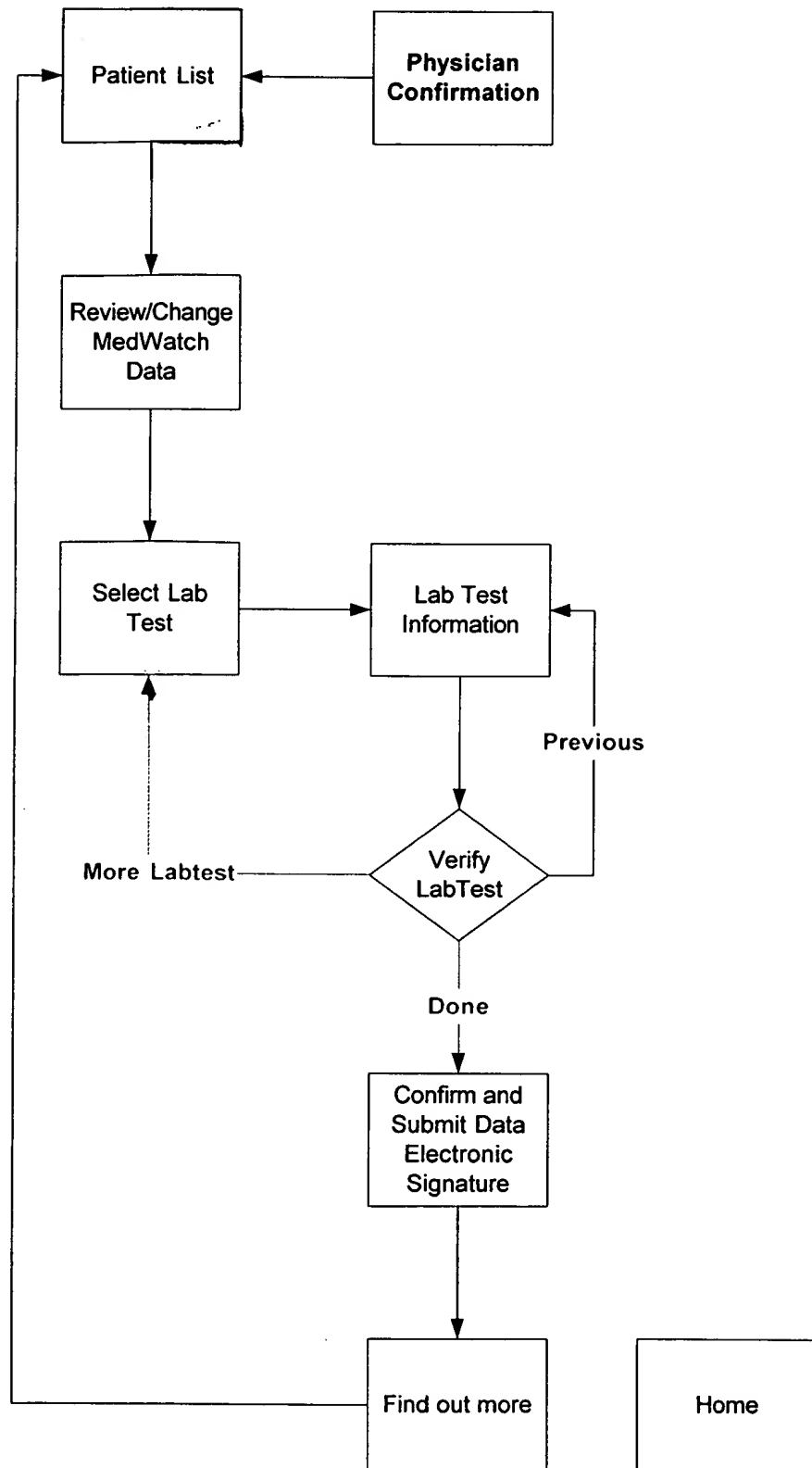


Fig 3b

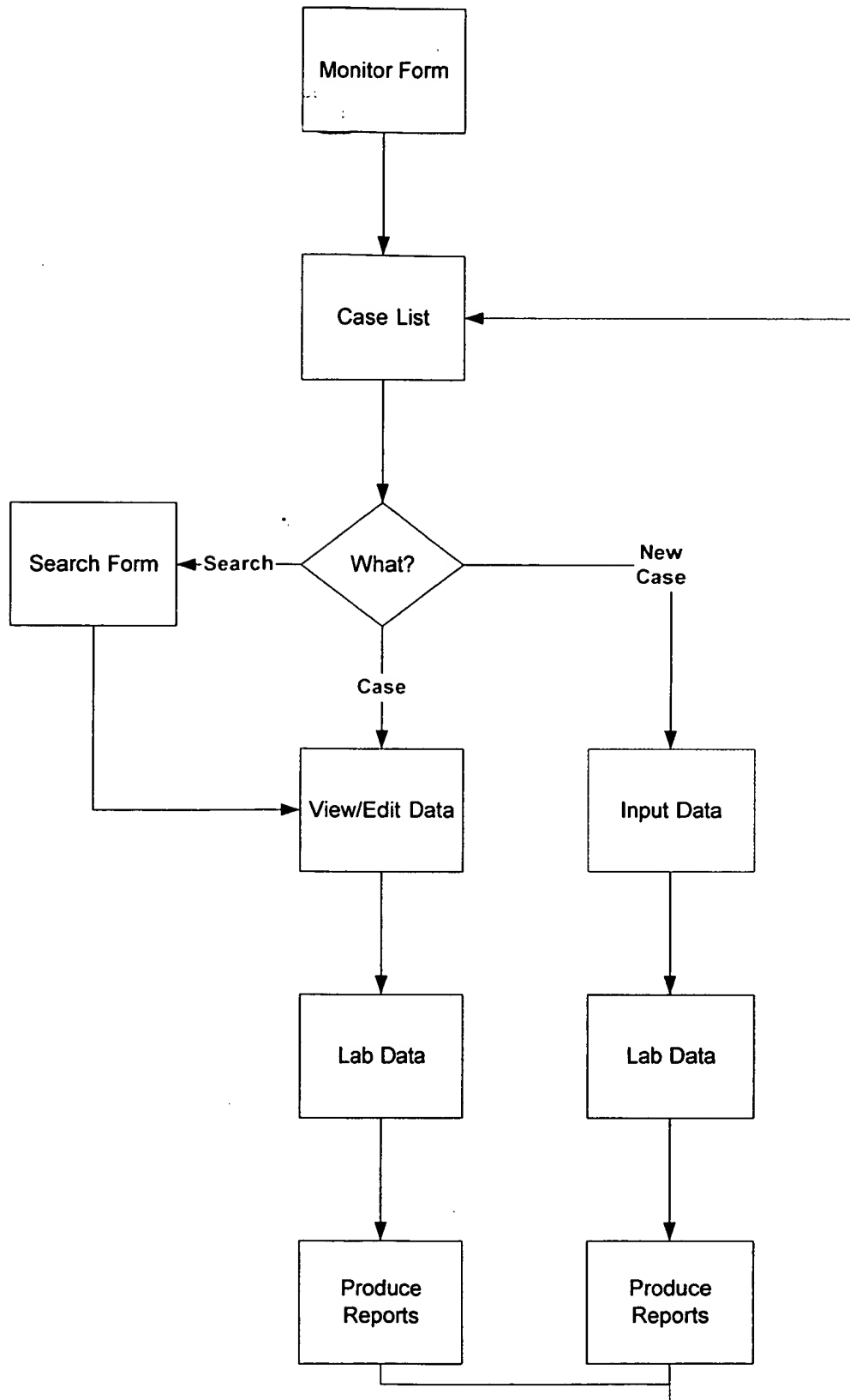
Physician Confirmation



405150" 4245860

Fig. 3c

Monitor Form



TEST 50" 4E455860

Home

Fig. 3d

Current Side Effects

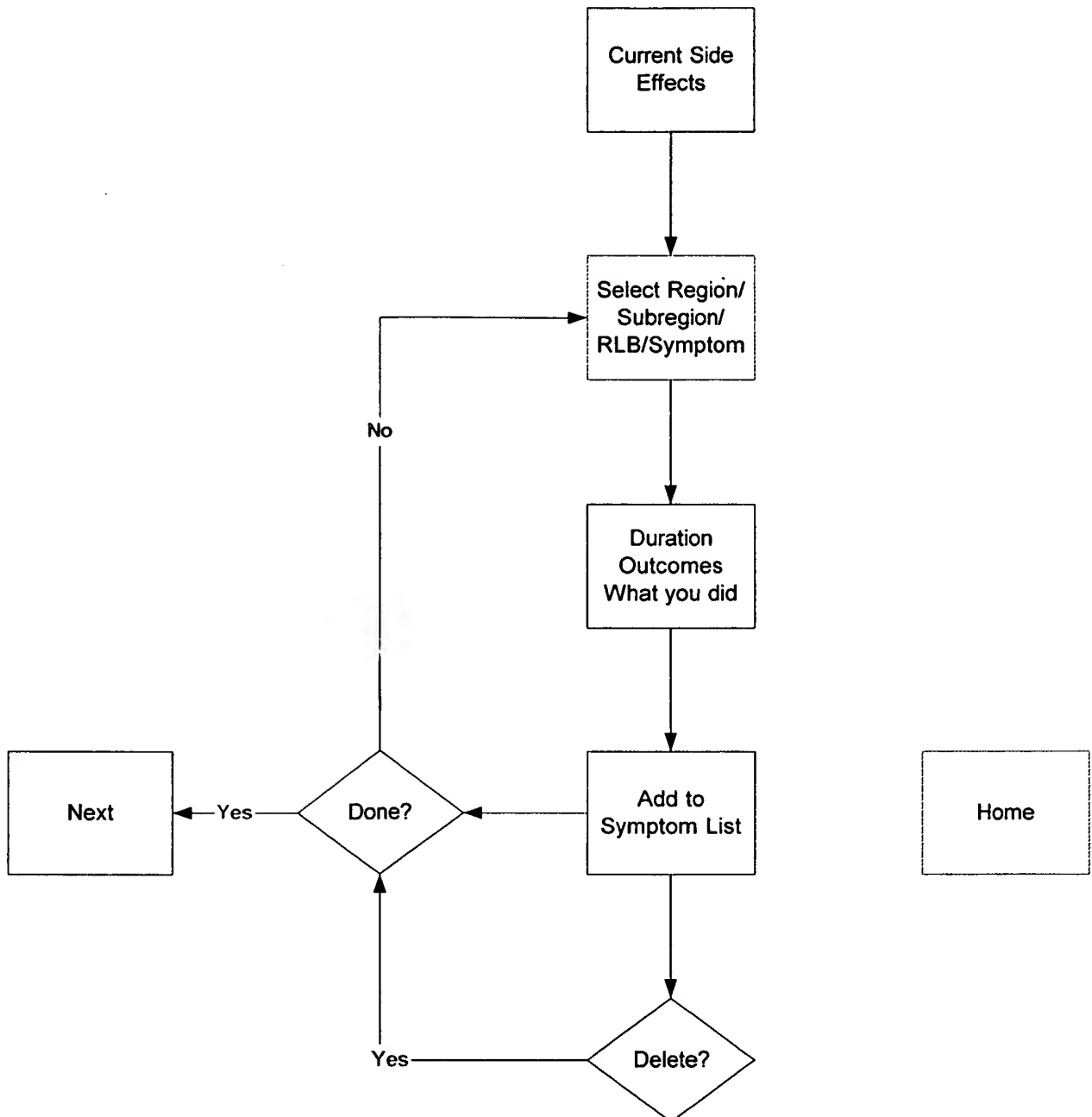
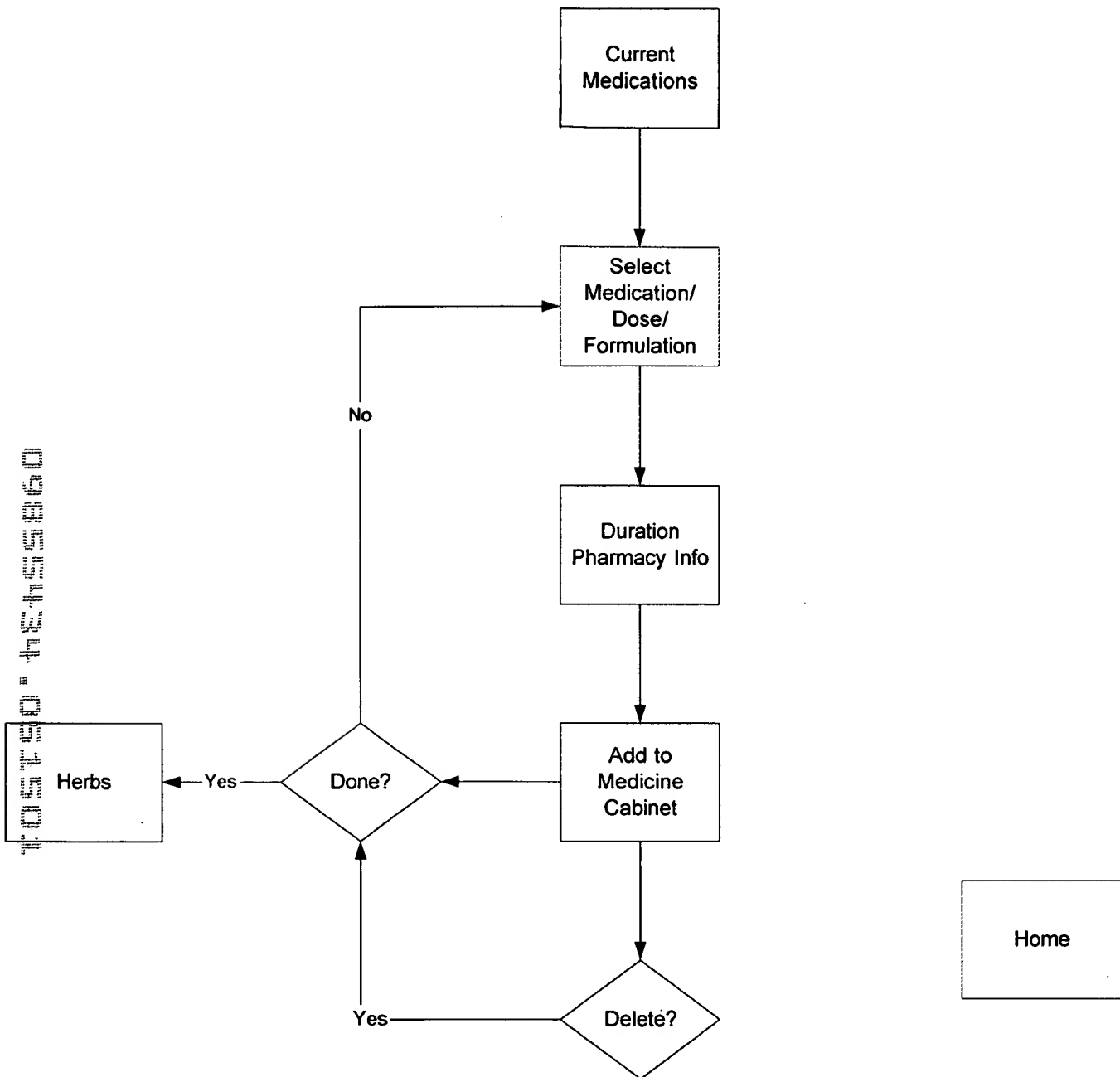


Fig 3e

Current Medication



Herbs and Nutritional Supplements

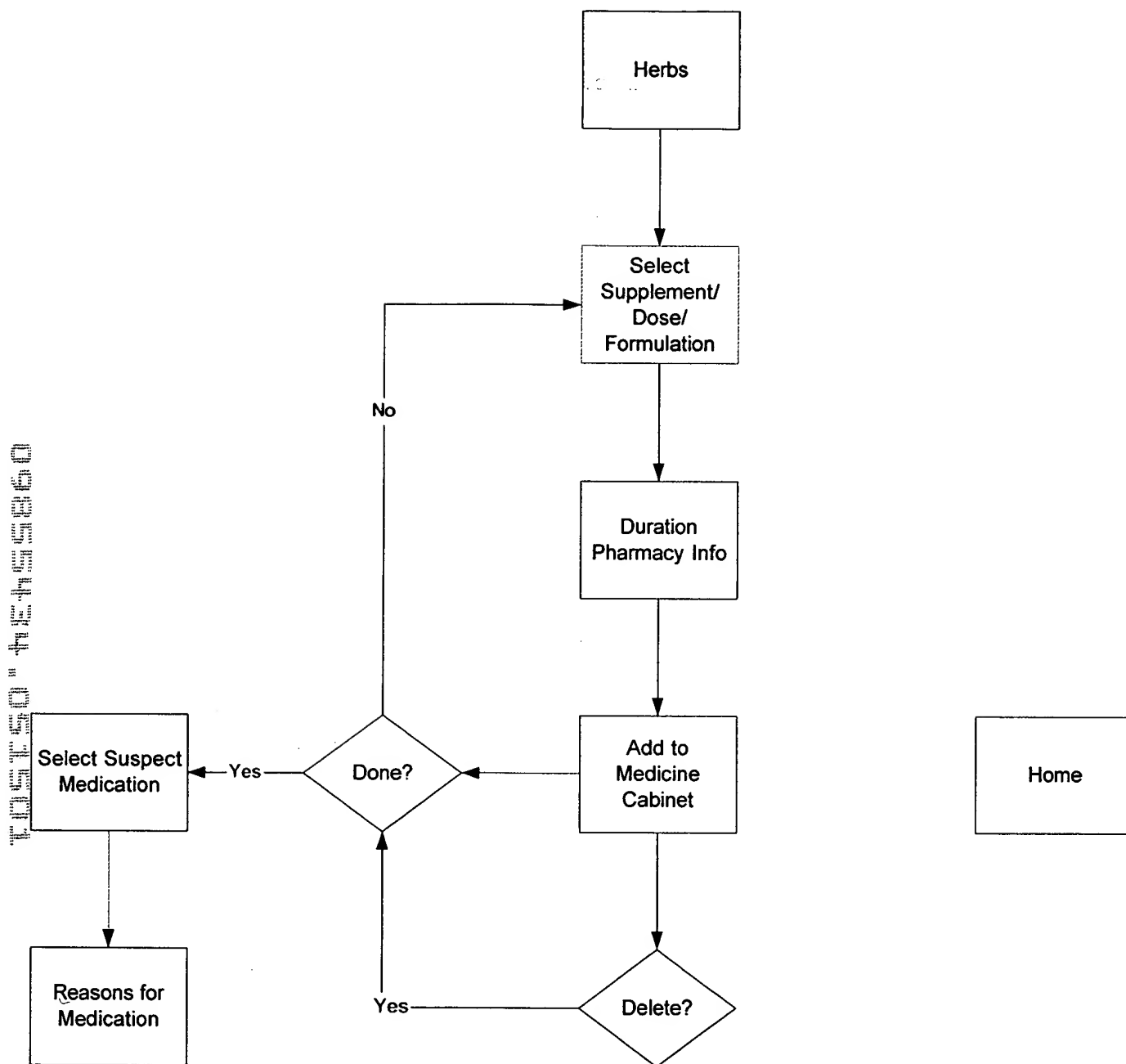
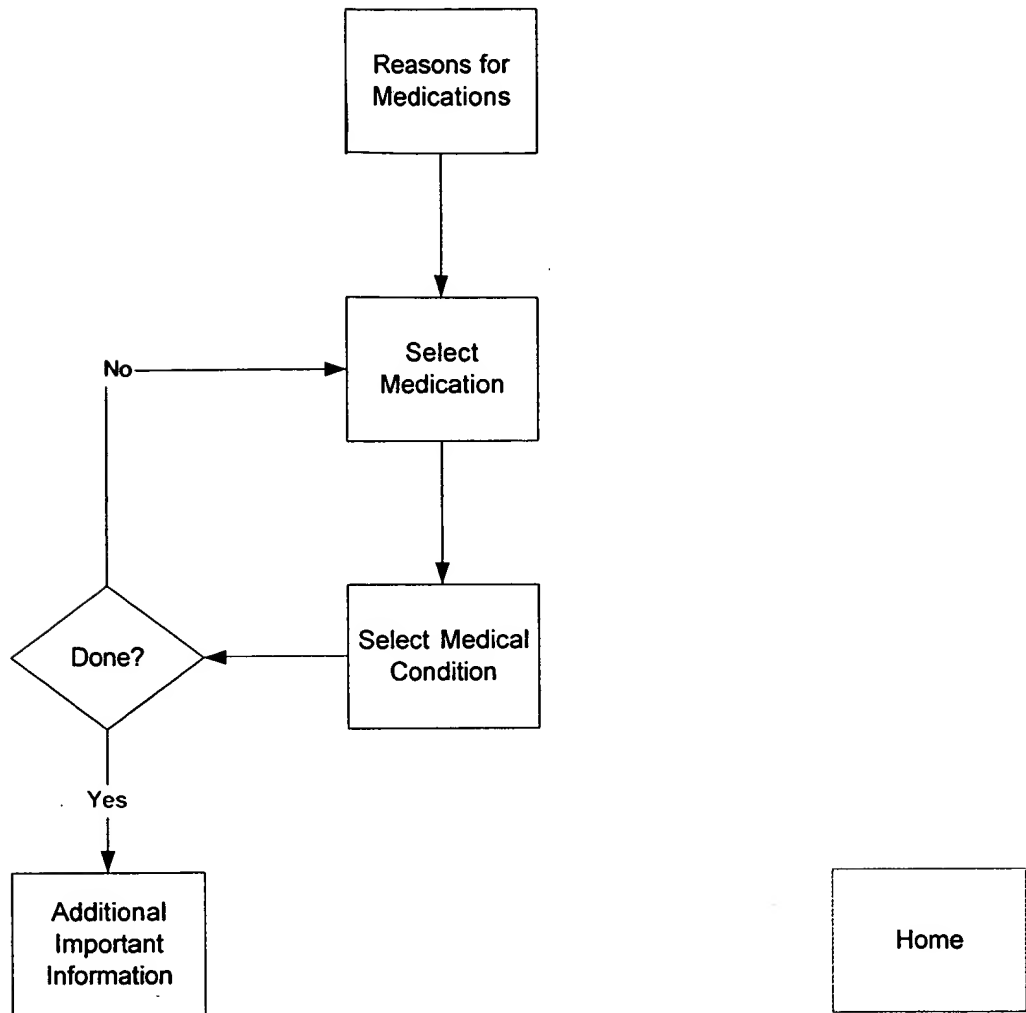
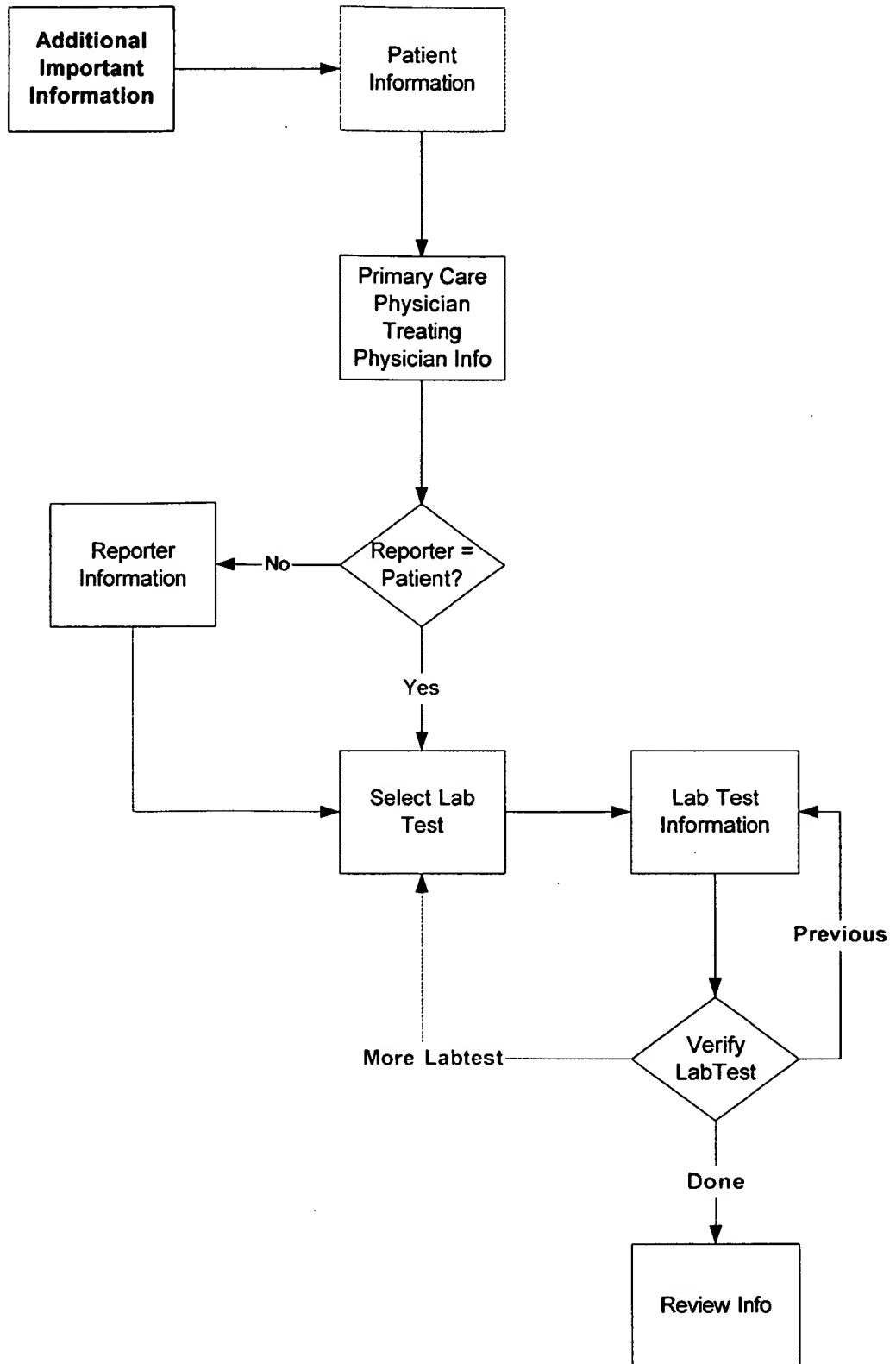


Fig. 39

Reasons for Medication



Additional Important Information



Home

Review Information and Find out More

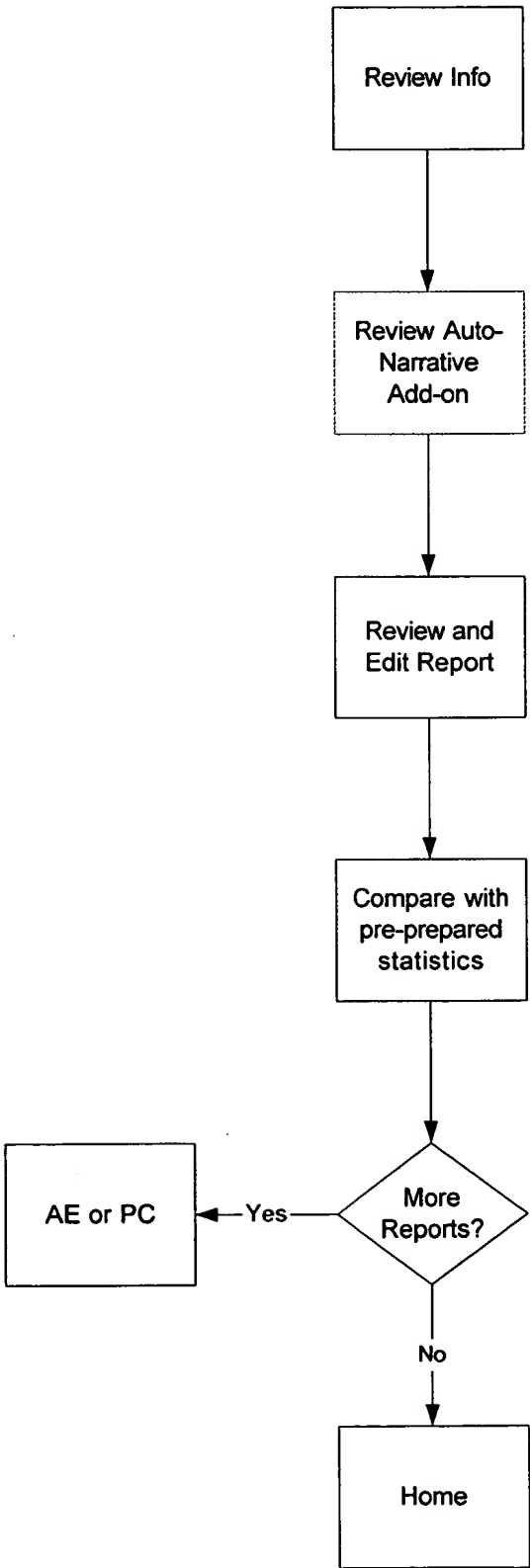


Fig. 30

09544-0501
TDS150-4245860

Product Complaint

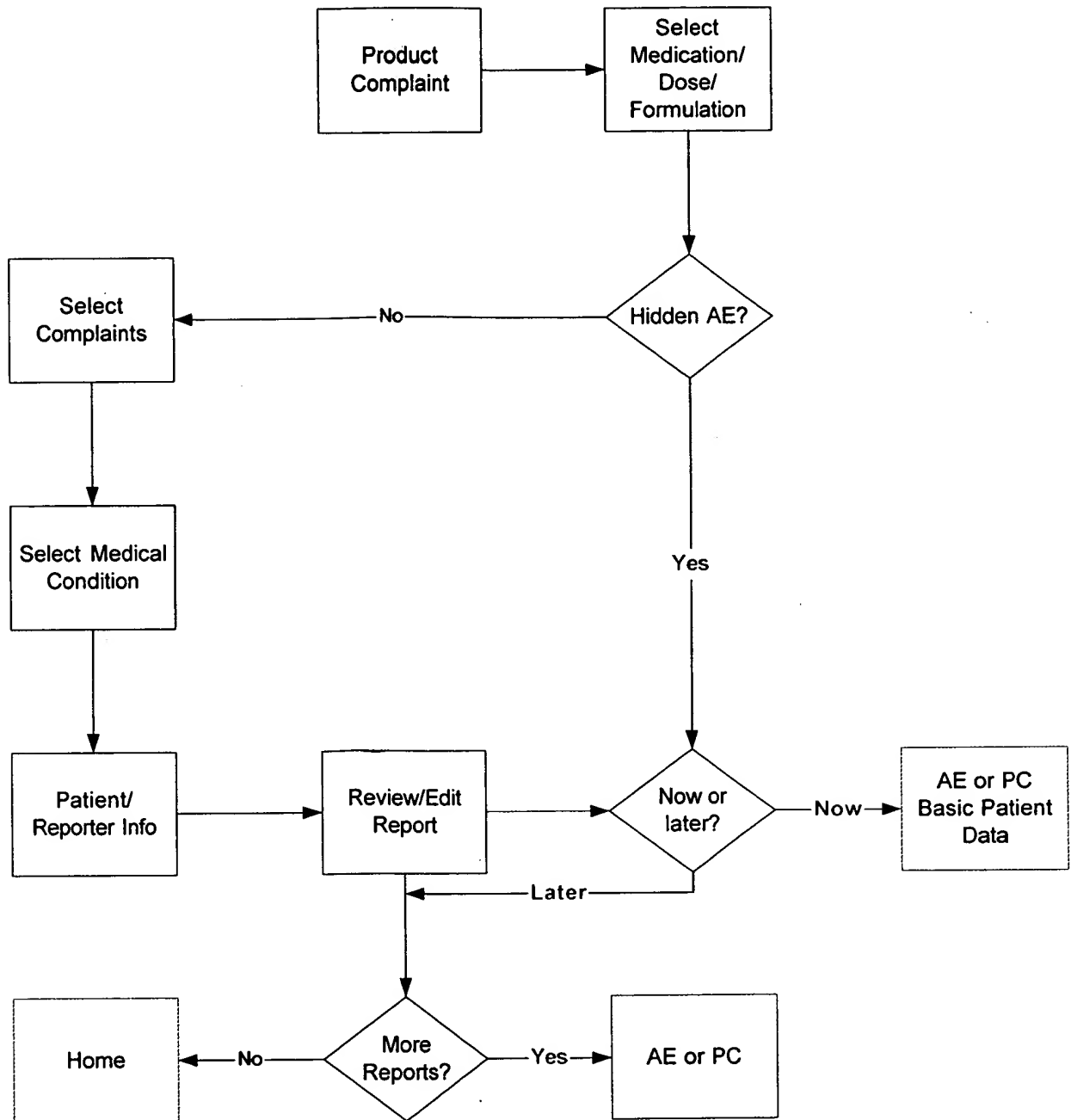


Fig. 3K



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Registration

Informed Consent

In order to complete the report, we may need to contact your physician. Your consent to contact your physician is called informed consent. Only your physician and you will see the information you provide us.

☐ Accept (required to proceed)

This Web Portal is super-secure. To see your information, define a User-ID and password and log in. Forget your password? We can re-create it: 1) define a secret question (ex: What is my favorite football team) 2) define a secret answer (ex: the SF 49ers). Together these will identify you.

For this pilot, type the 8 digit registration code printed on your trial card.

First Name	<input type="text"/>
Last Name	<input type="text"/>
User ID	<input type="text"/>
Password	<input type="password"/>
Password again	<input type="password"/>
Secret Question	<input type="text"/>
Secret Answer	<input type="text"/>
Phone Number	<input type="text"/>
E-mail	<input type="text"/>

1 Getting Started

- Login/Registration Instructions
- Who are you
- Side Effects and/or Product Complaints



Welcome to MyDrug Safety

Getting Started

First-time user? [Go to our registration page.](#)

You will need some information about your medication. As preparation, please get all your medication bottles, packets and containers.

Our reporting process contains 5 easy steps. At the end, you will receive a summary report for review.



The symbol provides online help. If you would like to read all the instructions for all the screens [click here to download.](#)

UserID and Password

UserID

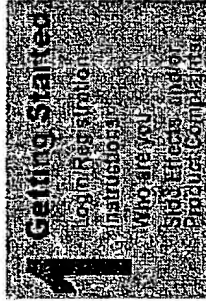
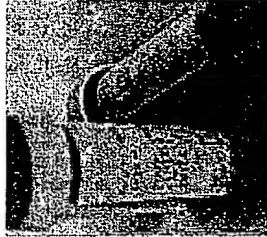
Password

Change your password?

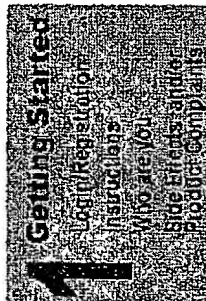
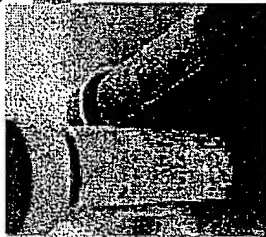
New Password

Repeat Password

[Next](#)



705750"4E45860



Patient-Physician Relationship

The Patient/Physician Relationship



To report your information properly, we have to have your physician confirm it. He will not only help you and us to make drugs safer, he can also help you with your side effect. Please provide us with your and your physician's information so that we can call or write back if we need more information. You can do this at any time by clicking on Registration or you will automatically be asked at the end of the process.

There appears to be an incomplete report in progress from the last time you were logged in. Do you want to recover it?

Clear

Recover

Fig 6



Instructions

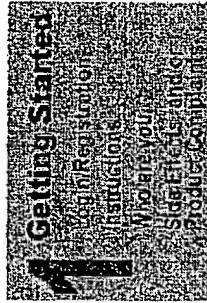
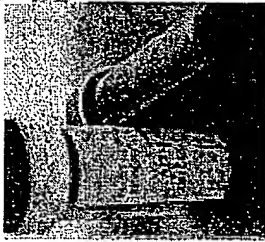
Easy steps to report a Side Effect or Adverse Event

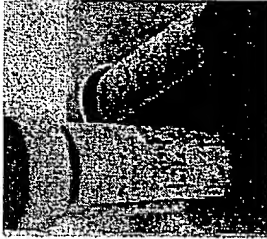
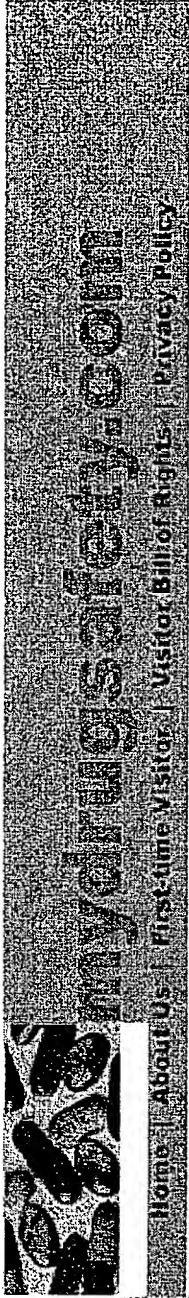
- STEP 1: Side effects or you are experiencing
- STEP 2: Medications you are taking
- STEP 3: Reasons for medication
- STEP 4: Additional important information
- STEP 5: Review your report and find out more

Easy steps to report a Product Complaint

- STEP 1: Product complaint
- STEP 2: Reason for medication
- STEP 3: Additional important information
- STEP 4: Review your report

Next





Who Are You?



Who Are You?

Family member/spouse

Patient Caretaker

Patient

Pharmaceutical Representative



Someone else? *Who?*

Treating physician

---Choose One---

Other Healthcare Professional

---Choose One---

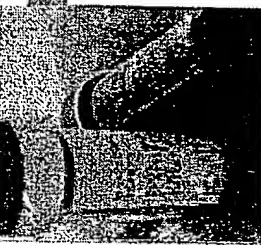



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Help

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Figure 8



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Adverse Event or Product Complaint?

What Do You Want to Report?



Adverse Reaction or a Side Effect you are having



Complaint about your medication

Family Members Data:

Date of Birth (mm-dd-yyyy)

or Age

Height feet inches
(ex: 5 feet 2 inches)

Weight lbs

Male

Female

Pregnant ☒ YES

Next



1

Getting Started

Log in/Registration
Instructions

Who are you?
Side Effects and/or
Product Complaints



Adverse Event Define a Symptom

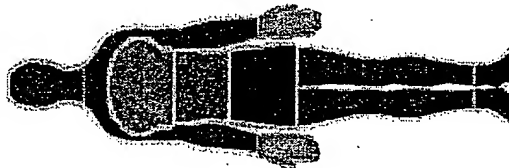
<p>Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.</p>		<p>?</p> <p>Delete</p> <p>Done</p> <p>To delete a symptom from highlight it and press Only when you have finished describing all your symptoms press</p>
<p>Click the region where the symptom occurs.:</p> <p>or</p>	<p>REGION Which area?:</p> <p>Anus Bladder Buttocks Cervix Groin Labia Minora/Majora Ovaries Rectum Uterus Vagina</p>	

- 1 Getting Started
- 2 Current Side Effects
 - What Symptoms
 - When Started/Ended
 - What Results
 - What You Did
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Renew Info & Find Out More



Adverse Event Define a Symptom

<p>Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.</p>		<p>?</p>
<p>To delete a symptom from highlight it and press</p> <p>Only when you have finished describing all your symptoms press</p>		<p>Delete</p> <p>Done</p>
<p>Click the region where the symptom occurs.:</p>	<p>REGION Which area?:</p> <p>Right-Buttocks Left-Buttocks Both-Buttocks</p>	



or

Fig. 10b

- 1 Getting Started
- 2 Current Side Effects
 - What Symptoms
 - When Started/Ended
 - What Result
 - What You Did
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

Fig. 102

General Body		<div><input type="checkbox"/> Congenital Anomaly</div> <div><input type="checkbox"/> Intervention Needed</div> <div><input type="checkbox"/> Life-Threatening</div> <div><input type="checkbox"/> Died</div> <div><input type="text" value=""/></div> <div>(mm-day-yyyy)</div> <div>Other <input type="checkbox"/></div> <div><input type="text" value=""/></div>	<div>Did it help? <input type="checkbox"/> YES</div> <div>Did something else</div> <div><input type="text" value=""/></div>
<div>Add Symptom to list</div>			


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Help

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- 1 **Getting Started**
- 2 **Current Side Effects**
- 3 **Current Medications**
Medications
Herbs & Supplements
Suggested Medication
- 4 **Reasons for Medication**
- 5 **Additional Important Information**
- 6 **Review Info & Find Out More**

Figure 11



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What Medication Are You Taking? Suspect Medication

<p>Please select the medication(s) that you think may have caused the event.</p>		?
<p>Your Current Medications Are</p> <p><input checked="" type="checkbox"/> Lamisil</p>		
<p>Previous Next</p>		

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
Medications
Herbs & Supplements
Suspect Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

Figure 12

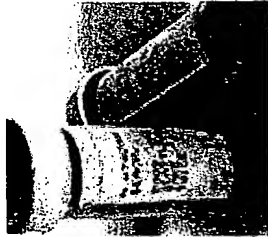


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What Medication Are You Taking?

Herbs or Nutritional Supplements



1 Getting Started

2 Current Side Effects

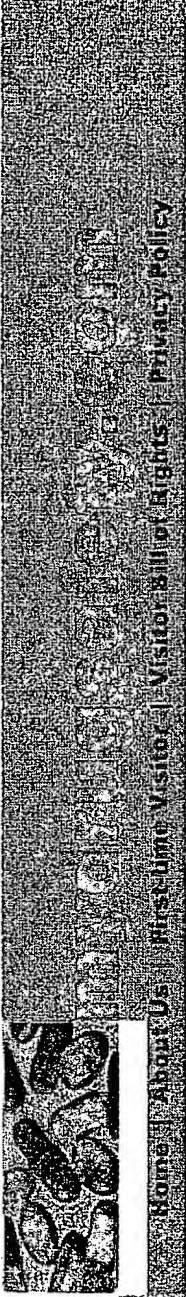
3 Current Medications
Medications
Herbs & Supplements
Problem Medication

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

<p>Tell us what herbs or other supplements you are taking.</p> <p>Click letter to choose from list. A B C D E F G H I J K L M N O P Q R S T U V W X Y Z</p>		<p>Your Current Herbs</p> <p>-----Your Current Medications----- &medicine1 &medicine1</p>	
<p>Pick one:</p> <p>-----select a medication-----</p>		<p>How long</p> <p>number of <input type="text"/> days</p>	
<p>Not on the list? Enter below</p> <p><input type="text"/></p>		<p>Need To delete a medication from your current list? highlight it and press</p> <p><input type="button" value="Delete"/></p>	
<p>What Dose</p> <p>-----select a dose-----</p>		<p>When your current medication list is complete press</p> <p><input type="button" value="Done"/></p>	
<p>Times a day</p> <p><input type="text"/></p>		<p>---optional info---</p> <p>Lot # of supplement? if present <input type="text"/></p>	
<p>What Formulation?</p> <p>-----what formulation-----</p>		<p>What Pharmacy did you you purchase it at? <input type="text"/></p>	
<p>name <input type="text"/></p>		<p>zipcode <input type="text"/></p>	



Adverse Event

What Are You Taking Your Medication For?

What condition are you taking your medication for? Click on your medication and a list of its associated condition/disease will appear. Select the appropriate one. Repeat for each medicine in the list.

Your Medication List			Medical Condition	
Medication	Formulation	Dose		
Lamisil	CREAM	1 %	<div>Frequency (Times a Day) 4</div>	<div>-----select only one----- Not on the list?...Enter below</div>

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Adverse Event Product Complaint

Check your record

This Report

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More
 - Review Alerts
 - Review Your Info
 - Other Similar Reports in the FDA

A -30Year old pregnant 1 patient, weighing 110 pounds, height 5 feet 6 inches, was taking Lamisil 1 & CREAM 4 Times a day since 07-01-2000, since [how long] [or continuing], for [indication/condition], reportedly experienced an event ['verbatim or reported' term/symptom (R/L/B)] on [date]. This report was received by [pharmaceutical company or GSS] on [date] from [reporter name].

The patient was also taking [prescription medication, over-the-counter or nutraceutical products: concomitant drug 1 (dose, formulation, number of times/day, how long or continuing) for (indication/condition); concomitant drug 2 (dose, formulation, number of times/day, how long

Anything to add?

Blablabla

Previous Next



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Review Your & Who Record Summary Report pat1 patlast

Review and edit your report,

?

- Getting Started
- Current Side Effects
- Current Medications
- Reasons for Medication
- Additional Important Information
- Review Info & Find Out More
Review Narrative
Review your info
When Similar Reports
to the FDA

Reports complete

Type over text to edit and only when complete press

A. Patient Information

Patient Name

Date of Birth

Age at Event

Gender

Pregnant?

Weight

Height

pat1 patlast

06-16-70

-30

☐ Male ☐ Female

☒ Yes ☐ No ☐ Unknown

110 Lbs

5 feet 6 inches
(ex: 5 feet 2 inches)

B. Adverse Event

Results

☐ Died On (mm-day-yyyy)

☐ Hospitalized Less than 24 Hrs

☐ Hospitalized over 24 Hrs

☒ Disability

☐ Congenital Anomaly

☐ Intervention Needed

☐ Life Threatening

☐ Other

Date of Event

(mm-dd-yyyy)

Date of Report

(mm-dd-yyyy)

01-23-2001

Description

Event Abated?

☐ Yes ☐ No ☐ Unknown

Event Reappeared?

☐ Yes ☐ No ☐ Unknown

C. Suspect Medications

Drug_Name	Dose	Therapy_Dates/Duration	Reason
Lamisil	1 %	From 07-01-2000 to 01-01-2001 Duration:1 Year	Disease 2

D. Concomitant Medication

Drug_Name	Dose	Therapy_Dates/Duration	Reason
-----------	------	------------------------	--------

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Help


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patientPortSM

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Arzneimittel-Nebenwirkungen Definieren Sie Das Symptom

Wir bitten Sie, im folgenden Ihre Arzneimittel-Nebenwirkungen zu beschreiben. Klicken Sie bitte eine Körperegion an und es wird eine Liste von Sub-Regionen erscheinen. Definieren Sie Ihr Symptom, indem Sie zuerst den genauen Ort bestimmen und dann ein Symptom aus der präsentierten Liste auswählen. Durch Anklicken der Figur können sie nachher weitere Regionen auswählen.	Klicken Sie bitte die Region, in der ihr Symptom sich aussert	KOPF Wählen Sie die Region?:	SYMPTOM Ihr Symptom	DAUER	WAS UNTERNAHMEN SIE DAGEGEN?
	AUGEN	VERENGTE PUPILLEN	VERENGTE PUPILLEN	DAUER Beginn des Symptoms mm-dd-yy Ende des Symptoms mm-dd-yy Wie lange dauerte es? Tage <input checked="" type="checkbox"/> JA Besteht das Symptom immer noch? <input type="checkbox"/> JA	<input type="checkbox"/> Nichts <input type="checkbox"/> Konsultierte einen Arzt <input type="checkbox"/> Stoppte die Medikamenten-Einnahme Reduzierte die Medikamenten-Dosis auf <input type="checkbox"/> Wechselte das Medikament auf Half es? <input type="checkbox"/> JA <input type="checkbox"/> Nahm das Medikament wieder und der Effekt erschien wieder
AUSWIRKUNG DES SYMPTOMS Hatte das Symptom direkte medizinische Auswirkungen, wie					

1 Start

Login/Registrierung
Benutzeranmeldung
Wer sind Sie?
Arzneimittel
Nebenwirkung oder
Beschwerde über ein
Arzneimittel

2 Arzneimittel-
Nebenwirkung

Ihre Symptome
Beginn und Ende
Direkte Auswirkungen
Geleitungsstörungen

3 Ihre
Medikamente

Medikamente
Andere Medikamente
Heilkräuter & Vitamine

4 Wechseln
nehmen Sie?

Fig. 16a

5 **Zusätzliche
Informationen**
Galerien-Daten
Arzte-Daten

6 **Bestätigen
Sie Ihre Daten**
Ihr generierter Bericht
Alle Ihre Daten
Vergleichen Sie/ändern
Berichten der FDA

FDOS 1.0

Hospitalisierung unter 24 Std

☐ Nalm ein Gegenmittel. Was?

SYMPTOM ZUR LISTE HINZUFÜGEN

Fig. 16a

00000440445360

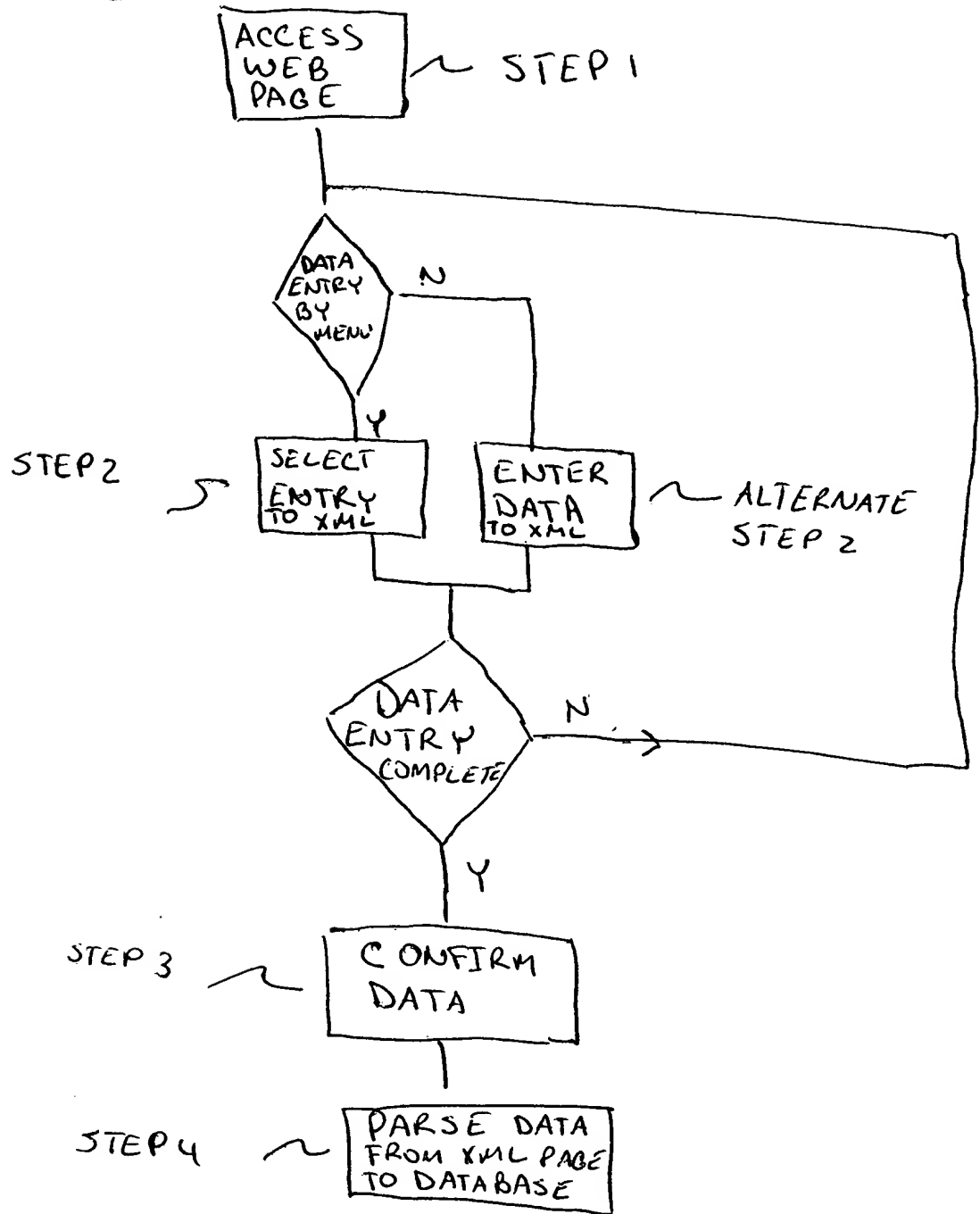


Figure 18